

REMARKS

Claims 1-17 were pending at the time of the Final Office Action and have been rejected as allegedly anticipated by or obvious over U.S. Patent No. 5,057,111 to Park. Claims 1 and 12 are currently amended, claims 2-11 and 13-17 stand as previously presented, and claims 18-20 are new. Reconsideration of this application is respectfully requested in light of the above amendments and following remarks.

I. Priority

The Examiner has requested a certified copy of the French application filed July 20, 2001, of which Applicant is claiming priority. Applicant is in the process of obtaining the certified copy and will forward it on to the Examiner at such time as it is obtained.

II. Specification

The Examiner objected to the disclosure of the specification based on informalities detailed in the Final Office Action. Applicant believes that the amendments to the specification offered above satisfy the Examiner's concerns. Accordingly, Applicant respectfully requests that this objection be withdrawn.

III. Double Patenting

The Examiner provisionally rejected claims 1-7 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 10,330,772. Applicant respectfully disagrees with the Examiner's assessment of the applications, including at least the Examiner's statement that the claims of the co-pending application "include more elements and are thus more specific" and the Examiner's conclusion that the co-pending application claims are a "species" of the "generic" invention of the present

application. However, Applicant is submitting herewith a terminal disclaimer, as suggested by the Examiner, to expedite prosecution in this case.

IV. Claim Rejections – 35 U.S.C. § 102

Claims 1-14 and 17 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,057,111 to Park. Applicant respectfully traverses and requests withdrawal of these rejections.

Applicant respectfully asserts that Park does not disclose all elements of independent claims 1 and 12. Applicant has amended independent claims 1 and 12 to clarify that the components of the devices are configured such that they allow articulation and rotation at the times of assembly and implantation. More specifically, independent claim 1 recites that either the fixed element of the mobile element is received in the internal volume of the intermediate element having mutual positions of use and introduction with three degrees of freedom in rotation at the times of assembly and implantation. Further, independent claim 12 recites that the socket member and the screw head are rotatable within the device with three degrees of freedom at the times of assembly and implantation. Conversely, Park's device is a rigid and fixed assembly which is clearly not designed to permit any rotation or articulation, particularly at the times of assembly and implantation.

In responding to Applicant's arguments, the Examiner states that Applicant is "reading" Park as it is attached to bone and that the present claims are directed to a device that is not attached to bone. Applicant respectfully disagrees with the Examiner's assessment of the Park reference and asserts that even upon *assembly* of the Park device (and prior to attachment to bone), the Park device does not allow for articulation and/or rotation of the components as recited in the claims. More specifically, it is clear from Park that its screw 35 does not have

three degrees of rotation relative to member 28 at either the time of assembly or implantation. Even assuming *arguendo* that the screw 35 could rotate about its longitudinal axis, the cylindrical collar between the head of the screw and its threaded shaft, and seated in the circular opening in the bottom of member 28, would prohibit any other rotation of the screw, for example in the plane of the page.

Additionally, Applicant respectfully asserts that upon *implantation* of the Park device in bone, that it is impossible for either the rigid plate 12 or screw 35 to rotate in three degrees of freedom with respect to member 28 and vice versa. Plate 12 of Park is placed so that it is rigidly fixed between the bone and the screw, so that force on the bone is transmitted through the screws to the plate, and all of the load is supported by the plate. Park's member 28 does not permit articulation of plate 12 relative to a screw, but performs exactly the opposite function. Member 28 is pressed between the screw head and the plate so as to transmit force from the bone through the screw to the plate, thereby removing a load from the bone upon implantation. If the member 28 were to permit articulation of the plate relative to the screw, load would not be diverted from the bone, which defeats the initial purpose for the plate and hinders healing or makes it impossible. Park's screw 35 also cannot rotate with respect to member 28 in three degrees of freedom because of the necessity of a tight, non-rotatory connection to the load transfer function of the screw and plate. The screws 35 are fixed such that no rotation within the members 28 is permitted.

It is only after an extended period of time that Park's member 28 shifts or resorbs so that contact is broken between the screws and the plate, and force on the bone is consequently not transmitted through the screws to the plate. However, while the connection between the screw and the plate may be broken, that does not inherently mean that the plate can be displaced

relative to a screw. Rather, one of ordinary skill in this art understands that when plates are fixed in contact with bone, as in the Park reference, tissue begins growing into the plate's pores and/or holes and around the plate, creating a natural grip of tissue on the plate. When some small space is created between the screw head and the member 28 in Park, and thus no force is transmitted to plate 12, there is still no displacement between the plate and the screw. It thus cannot be said that plate 12 is an element suitable for being displaced relative to the screw at any point in time. Additionally, once the member 28 of Park degrades, there is nothing remaining to permit any articulation. And the growth of tissue into and around the plate mentioned above does not permit the plate to articulate with respect to a screw.

For at least the reasons explained above, Park does not show or suggest the elements and their structural relationships at the times of assembly and implantation as recited in independent claims 1 and 12. Further reasons support the patentability of independent claims 1 and 12, as explained below.

Claim 1 additionally recites that the intermediate be deformable to be placed into the internal volume by *impaction*. Park's member 28 is not and cannot be placed in the plate 12 by impaction. As shown in Figures 2A-2C and described in paragraph 0035 of the present application, impaction indicates a deforming of the intermediate member as it is forced into the linking member. In Park, the member 28 is not placed by impaction, but is simply "disposed" in the hole in plate 12 (column 8, lines 5-9). The opening of the hole in the plate is the same size as the largest dimension of the member 28, and thus the only thing holding the member 28 in the hole is the screw 35.

Claim 12 additionally recites that the spherical screw head includes an *equatorial flat portion*. To satisfy this feature, the Examiner appears to be pointing to Park's cylindrical collar

between the head of the screw and its threaded shaft. Although the Park reference does not appear to discuss this item, Park's Fig. 5 clearly illustrates that this item is not equatorial, or positioned along the great circle on a sphere as that term is generally known. In other words, the cylindrical collar shown in Park is not positioned such that it is coincident with the equator or largest diameter of the screw head. Moreover, the cylindrical collar appears to be a separate component positioned below and not around the screw head at any position. Accordingly, Applicant respectfully asserts that Park's collar at the base of the screw head cannot reasonably be viewed as an equatorial flat portion, as recited in the claim.

Park does not anticipate or render obvious the features of independent claims 1 and 12. Claims 2-11 depend from claim 1 and claims 13-14 depend from claim 12, and accordingly those claims are also not anticipated by or obvious over the Park reference. Many of the dependent claims are patentable over the Park reference on their own merit as well. For example, dependent claim 9 recites that the spherical head has an equatorial flat portion. As stated above with regards to independent claim 12, Park does not disclose an equatorial flat portion about the spherical screw head. Additionally, dependent claim 11 recites that the linking member is separated from bone by the fixed element. As discussed and illustrated in the Park reference, the bottom surface of the plate contacts the bone directly and thus is not *separated* therefrom. More specifically, the specification states that "the bottom surface 16 is configured to rest against the bone 17." (Park, column 5, lines 64-68; column 6, lines 1-2). Additionally, dependent claim 13 recites that the equatorial flat portion is in a plane that is not perpendicular to the shaft axis of the screw. Oppositely, the Park reference illustrates that the cylindrical collar *is* perpendicular to the shaft axis of the screw. As another example, dependent claim 14 recites that the socket member deforms to be inserted and then reforms to its original shape. As stated above, there is no

discussion or suggestion in Park that member 28 deforms to be placed by impaction, but rather the specification only discusses the member 28 being "disposed" in the hole in plate 12 (column 8, lines 5-9). Dependent claim 17 includes numerous features not present in the Park reference as discussed above, including at least the socket member being deformable, the screw head having an equatorial flat portion, and the socket and screw head being rotatable with three degrees of freedom. For at least the reasons given above, Applicant respectfully asserts that claims 1-14 and 17 are patentable over Park and requests that the rejections be withdrawn.

V. Claim Rejections – 35 U.S.C. § 103

Claim 6 was rejected under 35 U.S.C. 103(a) as being unpatentable over Park. Claim 6 depends from independent claim 1. Accordingly, Applicant respectfully asserts that claim 6 is patentable for at least the reasons given above regarding claim 1 and requests that this rejection be withdrawn.

Claims 15-16 were rejected under 35 U.S.C. 103(a) as being unpatentable over Park in view of U.S. Patent No. 5,306,275 to Bryan. Claims 15-16 depend from independent claim 12 and thus Applicant respectfully asserts that the claims are patentable for at least the reasons discussed above in connection with independent claim 12. Applicant respectfully asserts that the rejection of claims 15 and 16 be withdrawn as well.

VI. New Claims 18-20

New claims 18-20 are being offered, as indicated above. Support for these claims is found throughout the specification and drawings. Discussion concerning the equatorial flat portions is found on page 4, paragraph 2, among other places, as well as at least Figs. 1, 3-4, 7-10 and 12. No new matter has been added.

Claims 18-20 are allowable over the Park reference and the other references of record for a number of reasons. Among these, claims 18 and 20 are dependent from independent claim 1 and claim 19 is dependent from independent claim 12, which are allowable as discussed above. The feature of the equatorial flat portion passing through the screw head's equator is also absent from Park, as is the feature of the equatorial flat portion lying in a plane oblique to the longitudinal axis of the shaft. For these and other reasons, it is submitted that neither Park nor the other references of record anticipate or render obvious any of the pending claims.

VII. Conclusion

It should be understood that these remarks are not intended to provide an exhaustive basis for patentability or concede the basis for the rejections in the Office Action but are simply provided to address those rejections in the most expedient fashion. Applicant reserves the right to later contest positions taken by the Examiner not specifically addressed herein, including arguing claims not specifically argued herein. The claims are intended to have the full scope afforded by their language, including equivalents.

Reconsideration in view of the above remarks and a Notice of Allowance is respectfully requested. If any further action would place this case in better form for allowance, the Examiner is encouraged to call the undersigned.

Respectfully submitted,

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